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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,844	03/04/2004	Peter G. Zaphiropoulos	2921-0145P	5375

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

SANG, HONG

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/10/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/791,844	Applicant(s) ZAPHIROPOULOS ET AL.	
	Examiner Hong Sang	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Zaphiropoulos et al.

1. Applicant's response filed on 2/20/07 is acknowledged. Claims 1, and 5-18 are pending. Claims 2-4 are cancelled. Claims 6-12 and 14-18 are withdrawn from further consideration. Claims 1, 5 and 13 are amended.
2. Claims 1, 5 and 13 are under examination.

Objections Withdrawn

3. The objection to the amendment to the specification filed on 3/4/04 because of the wrong page number is withdrawn in view of applicant's amendment to the specification.

Rejections Withdrawn

4. The rejection of claims 1-5 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "capable of participating in the human PTCH/SHH pathway" in claims 1-4 is withdrawn in view of applicants' amendment to claim 1 and cancellation of claims 2-4.
5. The rejection of claims 1, 5 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase "essentially comprised of SEQ ID NO.1" in claim 1 is withdrawn in view of applicants' amendment to the claims.

6. The rejection of claims 1 and 5 under 35 U.S.C. 102(e) as being anticipated by de Sauvage et al. (US Patent No. 6,709,838B1, Date of Patent 3/23/2004, earliest effective filing date 4/15/1998) is withdrawn in view of applicants' amendment to the claims.

Response to Arguments

7. The rejection of claims 1, 5 and 13 under 35 U.S.C.101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The response states that the specification as filed does in fact disclose, and provide evidence of, an activity for the protein, e.g. a comparison of the structure and function of human PTCH2 to human PTCH1 and mouse PTCH2, basal cell carcinomas (BCCs) show frequent mutations in the PTCH1 gene, and overexpression of PTCH2 mRNA. The response states that PTCH2 therefore has diagnostic value. The response states that PTCH2 gene has been localized to a chromosomal region often lost in tumors, PTCH2 is thus a candidate for a tumor suppressor gene. The response states that this region is also one to which three cancer disposition syndromes have been mapped, as a result PTCH2 is also a candidate for the gene behind these hereditary syndromes. The response states that de Sauvage's Patent (US 6,348,575) sets forth multiple uses for patched-2 such as used in screen assays to identify the molecules that interact with patched-2 protein or modulate the hedgehog signaling, and in making antibodies. The response states that Bumcrot (US patent 6,309,879) also disclose the

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patched-2 proteins can be used to screen for drugs which are either agonists or antagonists of ptc-2 protein. The response states that applicants have gone far beyond that is set forth in Example 4 of the Utility Guidelines, describing utilities specific to PTCH2.

Applicants' arguments have been carefully considered but are not found persuasive. While the specification discloses that the protein of SEQ ID NO.1, i.e. PTCH2 is 57% identical to PTCH1, with a significantly variable region present between the transmembrane domains 6 and 7, and 91% identical to the mouse PTCH2 sequence (see page 20, lines 26-29), as indicated in the previous office action, one of skill in the art cannot extrapolate the sequence homology data to the function of the PTCH2 protein, how the instantly claimed protein correlates to the human disease because the protein chemistry is unpredictable. It is known in the art that the relationship between the amino acid sequence of a protein (polypeptide) and its tertiary structure (i.e. its binding activity) are not well understood and are not predictable. While the specification teaches that mRNA expression is upregulated in BCCs, there is no indication that the PTCH2 protein expression is associated with BCCs. Furthermore, while PTCH2 gene is located to a chromosomal region often lost in tumors, even if we assume that the PTCH2 gene could be used for diagnosis of cancer, one skilled in the art still cannot conclude that the protein would be useful for diagnosis of cancer without the data showing that the PTCH2 protein is indeed expressed in the corresponding normal cells. In response to applicants' arguments that PTCH2 protein can be used in screening assays for identifying modulators or for making antibodies, these assays are

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not considered as specific and substantial utility given that the PTCH2 protein itself lacks utility.

8. The rejection of claims 1, 5 and 13 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained.

The rejection is maintained for the same reasons set forth above (see paragraph 7).

9. The rejection of claims 1, 5 and 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicants presented the same argument as set forth in utility rejection (see paragraph 7).

Applicants' arguments have been carefully considered but are not found persuasive. Specifically in the absence of a correlation between the claimed proteins and any diseases, such as cancer, the information obtained from over expression of the mRNA of PTCH2 in BCC only serves as the basis for further research on the observation itself. Therefore, absent evidence of the protein's expression including a correlation to any diseased state, one of skill in the art would not be able to predictably use the claimed proteins without undue experimentation.

Conclusion

10. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.

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March 27, 2007

A handwritten signature in black ink, appearing to read 'Chp H Y' with a stylized flourish at the end.

CHRISTOPHER H. YAEN
PRIMARY EXAMINER